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January 15, 2016

Pharmaceutical Working Group  
c/o Angelo J. Bellomo, REHS, QEP,  
Deputy Director for Health Protection  
5050 Commerce Drive  
Baldwin Park, CA 91706

Dear Mr. Bellomo:

Thank you for the opportunity to provide comments on the final draft *Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance*. We have twice provided public comments in consideration and support of your *Ordinance* and provided detailed written comments by letter dated October 23, 2015. We will not restate any of that which was communicated in that written testimony, but we would suggest that, where applicable, review of that testimony may be warranted.

**General Comments:**

Pharmacy take back of unwanted pharmaceuticals is an objective that we all should share. In striving for that objective, we should not forget that pharmaceuticals offer the most efficient and effective way to treat a number of diseases or bodily dysfunctions. To maintain that cost efficiency, any programs we undertake, such as your *Ordinance*, should seek to accomplish the stated goals at the lowest achievable cost.

It is important to recognize that the ultimate regulations that implement this *Ordinance* will be interpreted by, and have an impact on, the markets which will implement those regulations. In that regard, some market participants may view some of the requirements as onerous and unduly costly. To a certain extent, that is the challenge with any EPR initiative. In sharing your final draft *Ordinance* with market participants raised some questions as to their efficacy at a reasonable cost. In that regard, it may make sense to involve some of those market participants in your final drafting process to ensure that the ratepayers of LA County get the best value out of this *Ordinance*. Delivering a cost effective program, with active market based competition, has implications beyond LA County in that other jurisdictions are considering such Ordinances; to that extent, the most effective program will likely be mimicked by other jurisdictions.

In order to achieve both cost-effectiveness and operational efficiency, the ultimate desire should be a uniform system for all citizens. In that regard, you may want to consider a provision which enables a system merging with others such ordinances, regulations, laws, etc.

As a solid waste handling corporation, we, of course, have health and safety concerns about handling sharps at many of our facilities. That said, we do take sharps at several of our facilities, not in California, using specific protocols such as puncture proof containers, autoclave treated, and direct feed to the hopper. It appears that any mandated process regarding sharps should be protocol based. Extending the

protocol based strategy to manufacturers suggests that there are some opportunities with regard to sales including puncture proof disposal containers and having retractable points, for example. If indeed the solution is at the manufacturing level, this ordinance would not be a solution, but an extension of the dialogue. Finally, current California law would not allow Municipal Waste Combustors to provide end of life disposal for sharps; this suggests a potential need for state law modification.

**Specific Comments:**

Cytotoxic sharps - In the Ontario Sharps Collection Program, 6% of all sharps waste collected in the program by weight are cytotoxic sharps. These sharps are collected in clearly labelled cytotoxic sharps containers, segregated from biomedical sharps, over packed as cytotoxic waste and disposed of at a licensed biomedical waste incinerator. Unless addressed in the ordinance, it would need to be addressed in the regulations.

11.\_\_.020 "Mailer" Add 'and USPS' following 'FDA'.

11.\_\_.030 (d)(2) - It would appear that the communication with potential collectors should occur after the establishment and approval of a plan and that a listing of those contacted should be sufficient without the need for copies of all such notifications.

11.\_\_.040 (e), 11.\_\_.050 (b)(3) - We share with you the concern about protecting patient information; however, we should also recognize that this is a personal responsibility. In that regard, any program that mirrors the DEA drop off box should meet the standard for secure and appropriately destroyed. Please note that that system does not allow for the examination of deposited pharmaceuticals.

11.\_\_.040(h)(2) - While the objective of enhancing recycling and minimizing transportation and disposal costs is a laudable one, the proposed separation of drugs and sharps from packaging seems to both increase the probability of worker health and safety incidents as well as the potential for diversion. In addition, this objective appears in conflict with the DEA regulations which do not allow for handling of drop off product.

11.\_\_.060 (a) - This clause should be amended to have municipal waste combustors and hospital waste combustors on parity with hazardous waste combustors. The concept that these products require hazardous waste disposal increases costs unnecessarily with no consummate improvement in environmental health or safety. The argument could be made that the hazardous waste disposal preference is a less sustainable alternative to the extent that it mandates longer transport distances. These issues were addressed in our October 23, 2015 letter. While several entities have mandated such hazardous waste disposal or held it as a higher recommendation, for the most part, the lack of improved environmental performance with other MACT based combustors has been recognized, including by the US EPA.

11.\_\_.160 (a)(5) - This appears to be an excessive requirement of *Responsible Stewards* and appears more the purview of governmental entities. As such, the clause should be deleted.

Thank you very much for the opportunity to offer these comments. Following on our earlier written testimony, we continue to encourage dialogue with the various parties to ensure the most efficient and effective program that ultimately results in a reduction in drug poisonings in LA County and, hopefully, throughout the country. We will reiterate our suggestion of careful consideration of the costs of running

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such programs, since ultimately those costs are borne by all consumers. Finally, if we can be of any further assistance with regard to this consideration and any dialogue, we would be happy to do so.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Waffenschmidt', with a large, stylized flourish at the end.

John G. Waffenschmidt